IN THE COURT OF APPEALS
TWELFTH APPELLATE DISTRICT
BUTLER COUNTY, OHIO

LADONNA HOWLAND, et al.,

Plaintiffs/Appellees,

vs.

PURDUE PHARMA, L.P., et al.,

Defendants/Appellants.

Appeal No. CA 2002 09 0220

Trial Ct. Case No. CV2001 07 1651

CIVIL APPEAL FROM THE COMMON PLEAS COURT OF BUTLER COUNTY

BRIEF AMICI CURIAE OF AMERICAN PAIN FOUNDATION, NATIONAL FOUNDATION FOR THE TREATMENT OF PAIN, AND THE OHIO PAIN INITIATIVE, IN SUPPORT OF DEFENDANTS / APPELLANTS

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INTRODUCTION

The undertreatment of pain is widespread in Ohio. One of the primary reasons why tens of thousands of Ohioans needlessly suffer is physicians' fear that if they prescribe opioid analgesics in medically appropriate doses, they will become the target of legal sanctions. Amici curiae American Pain Foundation, *et al*., firmly believe that by certifying three plaintiff classes of sweeping breadth and indeterminacy, the decision below will have the unintended effect of depriving tens of thousands of legitimate pain patients, not party to this suit, of essential, and in many cases, life-saving medications. Amici, therefore, seek to provide this court with important information about the prevalence of chronic pain, the efficacy and relative safety of opioid analgesics as first-line treatments for this pain, the unfortunate stigmas and myths attached to opioid therapies, and the reluctance of the medical profession to adequately employ these therapies, so that this court will better understand the cause for and devastating impact of the medical consequences that will likely befall Ohio patients who suffer moderate to severe chronic pain if the class certification order is not overturned.

Amici are neither blind nor insensitive to the serious harms and substantial suffering caused by the misuse of OxyContin, particularly when this drug is obtained on the black market, outside of the physician-pain patient relationship. There is substantial evidence to suggest, however, that if this class action lawsuit is allowed to proceed, Ohio's physicians -- any one (or all) of whom could become the next target of a similar class action -- will be measurably deterred from treating moderate and severe pain not only with OxyContin, but with *any and all* Schedule II opioid analgesics, which by definition share the same potential for abuse as Oxycontin. In short, and as explained more fully below, this court should overturn the class certification order not simply because legal precedents warrant such a result, but because sound public health policy, and the medical well-being of Ohioans require it.

INTEREST OF AMICI CURIAE

Amici curiae American Pain Foundation ("APF"), the National Foundation for the Treatment of Pain ("NFTP") and the Ohio Pain Initiative ("Ohio Pain") are leading organizations at the national and state level devoted to the promotion of effective pain management. In addition, these organizations are committed to the ongoing education of the medical and legal professions and the public about the public health ramifications of untreated and undertreated pain and the effectiveness of Schedule II opioids to combat pain. Amici recognize the imperative of developing adequate medical responses to the needs of patients who suffer from chronic pain and are dedicated to fostering an environment where pain patients can obtain appropriate opioid therapy to prevent needless physical and mental anguish, prolong lives, and improve functioning and productivity.

The American Pain Foundation is the nation's largest nonprofit organization devoted exclusively to serving the needs of people with chronic and acute pain. APF's mission is to improve the quality of life for all Americans with pain through information, support, public outreach and advocacy. APF has assisted countless Ohio residents through its website, educational materials, toll-free number and other services.

The National Foundation for the Treatment of Pain is a national nonprofit organization dedicated to providing emotional and educational support for patients who suffer from intractable pain, as well as the families, friends, physicians and other health professionals who help care for them. NFTP's website, www.paincare.org, has proven a popular and important resource in this effort. NFTP counts among its members Ohio residents who suffer from untreated or undertreated chronic intractable pain.

The Ohio Pain Initiative, formerly the Ohio Cancer Pain Initiative, is a nonprofit corporation founded in 1991 and located in Columbus, Ohio, committed to ensuring that Ohioans who suffer from pain will receive optimum pain management. Ohio Pain, whose membership ranges from health care organizations such as Ohio Hospice and the Palliative Care Organization

to individual health care professionals, and pain patients and their families, was created in response to the needless suffering of thousands of Ohioans due to undertreated or untreated pain.

STATEMENT OF THE CASE AND STATEMENT OF FACTS

Amici curiae incorporate by reference the statement of the case set forth by Defendants-Appellants in their briefs.

ARGUMENT

I. OPIOID ANALGESICS ARE THE MOST EFFECTIVE TREATMENT FOR MANY CHRONIC PAIN PATIENTS BUT ARE TOO OFTEN WITHHELD FROM PATIENTS BECAUSE OF THE STIGMA AND FEAR ATTACHED TO OPIOID USE AND PRESCRIBING.

Chronic pain "is a destructive disease with physical, psychological, and behavioral consequences."[1] It is also a condition from which an estimated 50 million Americans suffer.[2] Such pain has myriad sources, including cancer, sickle cell anemia, severe back injuries, serious burns, or many other physical insults or diseases. Untreated pain costs the U.S. economy approximately $100 billion a year in lost workdays, excessive or unnecessary hospitalizations, unnecessary surgical procedures, inappropriate medication and patient-incurred treatment expenses.[3] Because the mental and physical anguish of chronic pain can be so debilitating,

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[1] See, e.g., Daniel Brookhoff, Chronic Pain: 1. A New Disease?, at http://www.hosppract.com/issues/2000/07/brook.htm

[2] Chronic nonmalignant pain "is defined by persistence [of pain] for one month or more beyond the usual course of an acute illness or injury, a pattern of recurrence at intervals over months or year[s], or by association with a chronic pathological process." New York State Public Health Council, Breaking Down the Barriers to Effective Pain Management: Recommendations to Improve the Assessment and Treatment of Pain In New York State 3-4 (1998) [hereinafter Breaking Down the Barriers].

[3] See id., at 3 ("Pain accounts for more than one quarter of workdays lost, increases health care utilization, and disrupts family and social functions."). See also Kathleen Doheny, Ouch! Pain Costs Employers $80 Billion Annually, Reuters Health (Aug. 21 2002) (citing Walter F. Stewart, et al., Work-Related Cost of Pain in the United

relieving it has been a core duty of physicians over the ages.

A. Opioids are the Most Effective Treatment for Many Patients Suffering Moderate and Severe Chronic Pain

Modern medicine has the ability to alleviate the suffering caused by nearly all types of pain.[4] "Since the 1980's, there has been a worldwide clinical consensus that opioid drugs[5] should be the first-line treatment approach for severe acute pain and moderate to severe chronic cancer pain."[6] "[F]or many patients opioid analgesics – morphine, oxycodone, Fentanyl patches, even methadone [] – are the most effective way to treat pain of moderate to severe intensity and often the only treatment that provides significant relief."[7]

By definition, all of the 58 opioid analgesics labeled Schedule II substances by the Controlled Substances Act, 21 U.S.C. § 801 et seq., have a "high potential for abuse." This abuse potential, however, is greatly reduced when opioids are prescribed by medical

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States: Results from the American Productivity Audit); Examining the Effects of the Painkiller OxyContin, Hearing Before the Senate Comm. on Health, Education, Labor and Pensions, 107th Cong., 74 (2002) [hereinafter Senate Hearing] (Testimony of Paul D. Goldenheim, M.D.).

[4] See Institute of Medicine Committee on Care at the End of Life, Approaching Death: Improving Care at the End of Life 132 (1997) [hereinafter Approaching Death]. The Institute of Medicine is an elite body of medical professionals "chartered in 1970 by the National Academy of Sciences to enlist distinguished members of the appropriate professions in the examination of policy matters pertaining to the health of the public." Id. at ii.

[5] "Opioids" constitute a class of natural and synthetic substances used medicinally to control pain. Although the term was originally used to refer only to synthetic compounds chemically similar to the natural opioids, such as methadone, current usage includes natural substances derived from the sap of the opium poppy, such as morphine, codeine, and oxycodone, the active ingredient in OxyContin. See Marc Galanter & Herbert Kleber, Textbook of Substance Abuse Treatment 191 (1994) (editors' note).

[6] Senate Hearing, supra, at 106 (Testimony of Russell K. Portenoy, M.D.).

[7] Senate Hearing, supra, at 41 (Statement of Richard Payne, M.D.). See also Aaron Gilson & David Joranson, Controlled Substances and Pain Management: Changes in Knowledge and Attitudes of State Medical Regulators, 21 J. of Pain and Symptom Management 227 (2001) ("opioids are essential for the management of moderate to severe acute pain").

professionals for the purpose of relieving moderate and severe pain.[8] Although the risk of opioid abuse is not zero in this context, medical leaders have come to understand that the small risk of abuse does not justify the withholding of these highly effective analgesics from chronic pain patients.

Opioid analgesics were first embraced by physicians to alleviate pain in terminally ill cancer patients facing imminent death.[9] Subsequently, the medical profession came to realize that these drugs were effective in treating the pain of non-terminal cancer pain patients, even when doing so required the administration of high doses over extended periods. In more recent years, research, clinical trials, and FDA approval of new medications have prompted physicians to extend the use of opioids to treat *non*-cancer pain.[10] This evolution of opioid pain care practices necessitated a full rethinking of long-held assumptions about opioids, principally the belief that opioids are too addictive or otherwise subject to abuse to be safely administered to any but the most seriously ill. But, as medicine has learned, pain is pain -- whether caused by cancer, traumatic injury, burns, or something else.[11] Accordingly, the factors that justify opioid therapy for cancer pain apply equally to alleviating moderate and severe chronic non-cancer pain.

Notwithstanding these advancements in palliative care, the majority of medical practitioners – not unlike the general public -- remain ignorant about the efficacy and relative safety of opioid analgesics to treat pain, and continue to labor under misconceptions about opioid addiction. As one pain specialist explains, "Opioids are our most powerful analgesics, but politics, prejudice and our continuing ignorance still impede optimum prescribing. What

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[8] See infra text accompanying notes 12-17.

[9] See Russell K. Portenoy & Richard Payne, Acute and Chronic Pain, in Substance Abuse, A Comprehensive Textbook 563, 567(Joyce H. Lowinson et al. eds., 1997) [hereinafter "Comprehensive Textbook"] ("Opioids are accepted treatment in cancer pain").

[10] Russell K. Portenoy, Opioid Therapy for Chronic Nonmalignant Pain: Clinicians' Perspective, 24 J.L., Med., & Ethics 296, 296 (1996.

[11] See Sandra H. Johnson, Disciplinary Actions and Pain Relief: Analysis of the Pain Relief Act, 24 J.L., Med. & Ethics 319, 324 (1996) ("Pain does not discriminate").

happens when opioids are given to someone in pain is different from what happens when they are given to someone not in pain. The medical use of opioids does not create drug addicts . . . ."[12]

B. Opioid Pain Therapy Can Cause Tolerance and Physical Dependence but Rarely Leads to Addiction

In a seminal report, the National Academy of Science's Institute of Medicine ("IOM") reported that "addiction in patients appropriately receiving opioids for pain is very small, ranging from 1 in 1,000 to less than 1 in 10,000."[13] Legitimate pain patients rarely seek the sense of euphoria that drug abusers do; in fact, pain patients often experience dysphoria (restlessness, depression, anxiety) from opioids.[14] The IOM found that pain patients do not become addicted even after receiving long-term, high-dose opioid therapy;[15] to the contrary, once pain subsides most patients voluntarily decrease or stop their opioid use.

A similar point was recently made at a U.S. Senate hearing devoted to the issue of OxyContin abuse. At that hearing Dr. Westley Clark, the Director of the Center for Substance Abuse Treatment ("CSAT"), a federal agency responsible for substance abuse issues, testified that:

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[12] Jane Brody, Misunderstood Opioids and Needless Pain, N.Y. Times, Jan. 22, 2002, at D8 (quoting Henry McQuay, M.D.).

[13] Approaching Death, supra, at 193. These numbers are comparable to the rates of addiction in American society as a whole. See Portenoy & Payne, supra, at 581. Cf. Richard Brown et al., Substance Abuse Among Patients with Chronic Back Pain, 43 J. of Family Practice 152 (1996) (finding chronic back pain did not connote special risk for current substance use disorders).

[14] Portenoy & Payne, supra, at 581.

[15] Approaching Death, supra, at 193 (citations omitted). See also, Portenoy & Payne, supra, at 581; John P. Morgan, American Opiophobia: Customary Underutilization of Opioid Analgesics, in Controversies in Alcoholism and Substance Abuse 171 (B. Stimmel, ed. 1986); Samuel Perry & George Heidrich, Management of Pain During Debridement: A survey of U.S. Burn Units, 13 Pain 267, 274 (1982); Jane Porter and Hershel Hick, Correspondence, Addiction Rare in Patients Treated with Narcotics, 302 New Eng. J. of Med. 123 (1980). See also Stuart Davidson, Pain and Opiophobia, 40 Healthcare Forum J. 64, 64 (May/June 1997) (reporting that the evidence to support the "fear that dosages large enough to relieve pain will cause addiction" is merely anecdotal).

> [T]he abuse of OxyContin is not primarily by those who are pain patients but by those who are opioid addicts.
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> [M]ost individuals who take their prescribed OxyContin, or any other opioid such as 2-hydrocodone or morphine, under medical treatment for pain, will not become addicted, although some may become physically dependent on the drug and may need to be carefully withdrawn after their pain problem is otherwise resolved. (Emphasis added).[16]

The CSAT recommendation to the Senate and to the public was clear:

> Patients who are taking these drugs as prescribed should continue to do so, so long as they and their physician agree that taking the drug is a medically appropriate way for them to manage pain. (Emphasis added.)[17]

Unfortunately, many politicians, law enforcement officials, journalists, pain patients, and medical practitioners fail to share this informed perspective and continue to labor under the misperception that prolonged use of OxyContin (or any other opioids) to treat moderate and severe chronic pain is likely to lead to addiction. This erroneous assumption is often fueled by the failure to distinguish between physical dependence on opioids and addiction to opioids.[18] "Because of the misconception by both clinicians and patients that physical dependence and addiction are interchageable terms, the use of narcotic analgesics in patients with acute or chronic pain remains inadequate at best."[19]

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[16] Senate Hearing, supra, at 24, 25 (Testimony of H. Westley Clark, M.D.). See also Eric Chevlen, A Bad Prescription from the DEA, The Weekly Standard, June 4, 2001, at 16, 17 ("virtually all of the oxycodone deaths are due to purposeful abuse of the drug").

[17] Senate Hearing, supra, at 25 (Testimony of H. Westley Clark, M.D.). Accord David Joranson et al., Trends in Medical Use and Abuse of Opioid Analgesics, 283 J. Am. Med. Ass'n. 1710, 1713 (2000) ("increasing medical use of opioid analgesics to treat pain does not appear to be contributing to increases in the health consequences of opioid analgesic abuse"); Peter Staats, Message from Southern Pain Society's President, APS Bulletin, at http://www.ampainsoc.org/pub/bulletin/sep02/reg2.htm("There is no reason to suspect that the prevalence of addiction is any higher in the pain clinic population . . . . [M]ost, if not all, of the cases [of OxyContin abuse] highlighted by the media have involved [illicit diversion of OxyContin]").

[18] Russell K. Portenoy & Seddon R. Savage, Clinical Realities and Economic Considerations: Special Therapeutic Issues in Intrathecal Therapy – Tolerance and Addiction, 14 J. Pain & Symptom Management S27, S34 (1997) ("[M]yths still exist regarding the use of opioids. Many clinicians continue to reject opioid therapy in patients for whom it is clearly appropriate, based on fears of iatrogenic addiction, the development of tolerance to drug effects, and physical dependence. These myths are perpetuated by imprecision in the nomenclature").

[19] Kathy Foley, The Treatment of Cancer Pain, 313 New England J. of Med. 84, 88 (1985).

Physical Dependence is a state of adaptation that is manifested by a withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist.[20] The ingestion of any opioid (and myriad other substances) can result in physical dependence. Caffeine is a common example of a drug that can produce dependence, as evidenced by the fact that many regular coffee-drinkers experience withdrawal symptoms, such as headaches, if deprived of their brew.[21] That is why, in the context of opioid pain therapy, medical guidelines call for physicians to slowly "titrate" the opioid at the start of treatment in order to achieve the optimum dose, and then slowly "wean" the patient from the opioid over a period of days or weeks at the conclusion of treatment. When the dose is tapered gradually, pain patients usually have little difficulty decreasing, and then stopping their opioid intake – be it OxyContin, morphine, or any other Schedule II analgesic -- so long as the underlying pain being treated has subsided or ceased.[22]

Addiction, on the other hand, is a primary, chronic neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. Addiction is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving.[23]

The confusion between physical dependence and addiction is commonplace. Many pain

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[20] Am. Acad. Pain Management, Definitions Related to the Use of Opioids for the Treatment of Pain: A Consensus Document, available at http://www.ampainsoc.org/advocacy/opioids2.htm [hereinafter "Consensus Document"] (providing consensus definitions of American Academy of Pain Management, American Pain Society, and American Society of Addiction Medicine).

[21] See John F. Greden & Adale Walters, Caffeine, in Comprehensive Textbook, supra, at 294, 295.

[22] See Portenoy & Payne, supra, at 564; Institute of Medicine, Federal Regulation of Methadone Treatment 10 (1995) ("The pain patient . . . . will develop tolerance and physical dependence but will not exhibit the illicit or inappropriate drug-seeking behavior.").

[23] Consensus Document, supra. See also, Portenoy & Payne, supra, at 564 (characterizing addiction as "a psychological and behavioral syndrome in which there is drug craving, compulsive use, and a strong tendency to relapse after withdrawal, [combined with] rumination about the drug and an intense desire to secure its supply"); id. ("[A]ddiction is a chronic disorder characterized by 'the compulsive use of a substance resulting in physical, psychological or social harm to the user and continued use despite that harm") (citing AMA task force).

patients (like daily coffee drinkers) claim they are "addicted" when they experience withdrawal symptoms associated with physical dependence as they decrease their dose. But unlike actual addicts, such individuals, if they resume their opioid use, will only take enough medication to alleviate their pain, but no more to intentionally get "high."

C. Continuing Ignorance About Opioids Has Resulted in their Stigmatization and the Gross Undertreatment of Pain.

It has been extensively documented that a lack of public and professional understanding about the nature of pain therapy – particularly when expressed through the uninformed actions of a few regulatory authorities that seek to restrict the use of opioid analgesics – has greatly impeded pain care. A substantial and consistent body of research indicates that clinicians are deterred from prescribing opioids out of concern that doing so will invite regulatory scrutiny[24], even for patients who are dying.[25]

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[24] See, e.g., Approaching Death, supra, at 195 ("There is still, it seems, an inappropriate sense of distrust on the part of the medical boards [regarding prescription of opioids for pain], which this committee believes has developed, in part, on the basis of misperceptions . . . about the nature and consequences of dependence and addiction."); Breaking Down the Barriers, supra, at 10; Aaron Gilson & David Joranson, supra, at 228 ("Physicians' concerns about being investigated by controlled substances agencies or state medical boards . . . can negatively affect prescribing practices"); Russell K. Portenoy, supra, at 297; Am. Soc'y. of Addiction Med. Position Statement (April 1997) ("[P]hysicians' concerns regarding possible legal regulatory, licensing or other third-party sanctions related to the prescription of opioids contribute significantly to the undertreatment of pain."); Robyn S. Shapiro, Health Care Providers' Liability Exposure for Inappropriate Pain Management, 24 J.L. Med. & Ethics 360, 363 (1996) (noting "fear of legal penalties, especially disciplinary action," as important reason for under-treatment of pain); Undertreatment of Pain Seen as Unintended Effect of Drug War, 9 Alcoholism and Drug Abuse Week 1 (June 23, 1997) (noting that "fear of professional censure by medical review boards and prosecution by the [DEA] . . . prevents doctors from adequately treating dying patients with chronic, severe pain.") (citing Dr. Christine Cassell); Davidson, supra, at 64-67 ("Physicians who would depart from prevailing cultural practices [regarding opioid prescription for pain] are quickly penalized, adding fear of repercussions (legal and otherwise) to the list of reasons why physicians may withhold narcotic pain relief."); Johnson, supra, at 320. See also Hoover v. Agency for Health Care Admin., 676 So. 2d 1380, 1382 (Fla. App. 1996) (noting that physicians avoid treating pain patients "perhaps to avoid prosecutions"); id. at 1381 n.4 ("Many physicians avoid caring for patients who require Schedule II substances to relieve their suffering.").

[25] See e.g., Approaching Death, supra, at 131; The SUPPORT Principal Investigators, A Controlled Trial to Improve Care for Seriously Ill Hospitalized Patients: The Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments (SUPPORT), 274 J. Am. Med. Ass'n 1591, 1591-93 (1995); Robyn S. Shapiro, Health Care Providers' Liability Exposure for Inappropriate Pain Management, 24 J.L. Med. & Ethics 360, 360 (1996); Ben A.

As a result, the United States is in the midst of "an epidemic of undertreatment of pain,"[26] – an epidemic rooted in physicians' reluctance to adequately treat pain by prescribing the opioid analgesic medicines available to them. To offer but one tragic example of this epidemic: in 1998 it was reported that 42% of terminally ill cancer patients in nursing homes received inadequate pain care and 26% of such patients received no analgesics at all, not even aspirin.[27] That the federal Drug Enforcement Administration, the principal agency charged with policing federal narcotics laws, has voiced concern about this state of affairs is a testament to the magnitude of this health problem.[28]

Notably, Ohio has been plagued by "opiophobia"[29] – the unfounded fear of the medical use of opioids -- long before and quite independent of any specific concerns about OxyContin. Consequently, many if not most of the state's residents have been deprived of adequate pain care. This fear of opioid analgesics has manifested itself in both law and medical practice. As of 1995, Ohio was one of only two states that prevented opioids from being prescribed to treat chronic non-cancer pain until other treatments were first attempted.[30] Though these restrictions

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Rich, A Legacy of Silence: Bioethics and the Culture of Pain, 18 J. Med & Human. 233 (1997).

[26] Senate Hearing, supra, at 33 (Testimony of H. Westley Clark, M.D.).

[27] Roberto Bernabei et al., Management of Pain in Elderly Patients with Cancer, 279 J. Am. Med. Ass'n. 1877 (1998). See also American Bar Association Commission on Legal Problems of the Elderly Report to House of Delegates, available at http://www.abanet.org/aging/ (collecting data on undertreatment of pain among the elderly).

[28] Drug Enforcement Administration, DEA to Join Pain Advocates In Issuing Statement on Prescription Pain Medications (Press Release) (Oct. 23, 2001) [hereinafter Press Release], at http://www.usdoj.gov/dea/pubs/pressrel/pr102301.html ("Undertreatment of pain is a serious problem in the United States, including . . . those who are critically ill or near death.").

[29] See Morgan, supra, at 163; Rollin Gallagher, Outcomes and Moral Hazards in the Medical Culture of Opioid Phobia, 14 Clinical J. of Pain 185 (1998) (noting "the cultural party line that opioids are anathema to the 'moral' care of the patient and unsafe medically" is no longer tenable).

[30] David Joranson et al., Pain Management, Controlled Substances, and State Medical Board Policy: A Decade of Change, 23 J. of Pain and Symptom Management 138, 142 (2002) (quoting State Medical Board of Ohio, Scheduled Drug Therapy Including Narcotics for Chronic Benign Pain, Your Report, 3-5 (1995)).

were subsequently lifted, little changed with respect to how physicians dealt with patient pain. A 2002 study by Last Acts, a Robert Wood Johnson Foundation campaign to improve end-of-life care, ranked Ohio near the bottom with respect to the treatment of persistent or chronic pain. The study found that in the year 2000 only 53.8% of hospitals in Ohio offered pain management programs in 2000, and that in 1999 44% of the state's nursing home residents suffered persistent pain. Ohio received a grade of "D" for several key indices, including its policies regarding pain management and the availability of hospice care. Ohio's overall pain care policies received a score of "0" on a scale of –2 to +9.[31]

D. The Media Has Perpetuated Myths and Fears About OxyContin in Ohio That Threaten to Jeopardize the Treatment of Pain.

Against the backdrop of "opiophobia" the stage was set for the inaccurate and often inflammatory reporting that accompanied the advent of OxyContin diversion and misuse. If "America is a country where the treatment of pain is governed by how we perceive the drug-abuse problem"[32] (and experience suggests that it is), then the fear of OxyContin abuse, as exacerbated by numerous press accounts, threatens to reverse the important advances made in the field of palliative care.

In criticizing the media's general handling of the OxyContin issue, amici do not deny that the illicit use of OxyContin has caused significant harm, including death; nor do amici intend in any way to minimize the suffering that many people have experienced as a result of OxyContin misuse. Rather, amici simply wish to observe that the media, particularly that of Ohio and of

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[31] Last Acts, Means to a Better End: A Report on Dying in America Today, (Nov. 2002), available at, http://www.lastacts.org/scripts/

[32] Damien Cave, No Relief, Salon.Com (Apr 4, 2002) [hereinafter No Relief] (quoting David Joranson), http://www.salon.com/mwt/feature/2002/04/04/no_relief/index.html

neighboring Kentucky, have reported about OxyContin with heated rhetoric and partial truths that have fueled a public hysteria about the drug that has affected the attitudes -- and behaviors -- of law enforcement, pain patients, and medical practitioners.[33]

Whether OxyContin is called the "killer high" on the CBS Evening News[34], or "hillbilly heroin"[35], or described (as it was in a front-page story in the Columbus Dispatch) as the drug that "snaked its way into Ohio . . . where it poisoned Ohio river towns,"[36] to become "the street drug of choice" – the overall tenor of the reporting has been to reinforce the erroneous belief that OxyContin users suffer from addiction and related harms in significant and growing numbers. Many of the commonly cited statistics about OxyContin-induced deaths, robberies, consumption and dealing have been criticized by many neutral onlookers, who additionally point out that most media coverage has minimized – or omitted -- the fact that the vast majority of harms caused by OxyContin result not from its legitimate medical use by patients, but from its misuse and abuse by people who obtain it illegally, and who often ingest it in combination with other drugs or alcohol.[37]

In the rare cases when the media does profile pain patients, it tends to select patients who

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[33] Press Release, supra ("repeated accounts of misuse have skewed peoples' perceptions about drugs like OxyContin") (quoting Russell Portenoy, M.D.).

[34] Cynthia Bowers, Trail of Addiction and Death Spreading from use of the Powerful Cancer Pain Drug OxyContin, (CBS Evening News television broadcast, Feb. 9, 2001).

[35] See A Painful Abuse: Addicts' Use Hurts Legitimate Patients, Too, Columbus Dispatch, Oct. 2, 2001, at 8A [hereinafter Addicts' Use Hurts Legitimate Patients] (noting that the media has given OxyContin this "unfortunate moniker"in Ohio, Kentucky and other parts of Appalachia).

[36] Misti Crane and Bruce Cadwallader, More Overdose Deaths Blamed on Painkiller, Columbus Dispatch, Jan. 6, 2002, at 1A.

[37] See generally Chevlen, supra, at 17; Sandeep Kaushik, Oxycon Job: The Media-Made Oxycontin Drug Scare, Cleveland Free Times, May 2, 2001 [hereinafter Oxymorons] (documenting the "prominent", "alarmist", "sensationalized, fear-mongering" coverage of OxyContin by the Ohio press), available at, http://www.freetimes.com/issues/933/features-coverstory.php3.

are quick to warn against OxyContin's extreme dangers, mistaking their symptoms of opioid dependence for hallmarks of OxyContin addiction. The media's conflating physical dependence and withdrawal by pain patients with the addiction resulting from illegal OxyContin use has negatively influenced patients, law enforcement, and healthcare professionals who all report "fear of addiction" as a major barrier to treating acute and chronic pain patients with any opioid.[38]

II. THE CLASS CERTIFICATION WILL DETER MANY OHIO PHYSICIANS FROM PRESCRIBING ANY SCHEDULE II OPIOIDS – NOT JUST OXYCONTIN – THEREBY EXACERBATING THE UNDERTREATMENT OF PAIN

A. The Class Definitions Make a Potential Target of Virtually Every Ohio Physician Who Has Ever Prescribed OxyContin and Will Prompt Many Physicians to Repudiate It.

If the class certification is not overturned on appeal, many Ohio physicians will be deterred from prescribing OxyContin or other opioid analgesics to patients in moderate and severe pain. Because the class definitions lack any discernible limiting principle, if the class action is allowed to proceed every Ohio physician who has written even one OxyContin prescription would have reason to fear liability in a future such case. The classes certified below do not and cannot account for the inherently individualized decision to prescribe one pain medication over another.

"The available data suggest that medical decision-making regarding the use of opioids continues to be unduly influenced by regulatory policies or fear of regulators."[39] Physician

[38] See, e.g., Addicts' Use Hurts Legitimate Patients, supra.

[39] Russell K. Portenoy, Opioid Therapy for Chronic Nonmalignant Pain: A Review of the Critical Issues, 11 J. Pain and Symptom Management 203, 204 (1996).

attitudes, in other words, remain strongly biased toward personal risk reduction and away from pain alleviation.[40]

> [H]owever weak the factual foundations, the anxieties felt by physicians and other health care providers about potential criminal, civil, and/or regulatory liabilities are real and palpable influences on the quality and humanity of medical care actually provided to the most vulnerable patients. This is true even for those physicians who understand that their own legal exposure is minimal. The very fact that physician conduct in this most delicate of areas could conceivably be questioned in a legal context is enough to skew behavior.[41]

This class action lawsuit carries an analogous type of exposure and liability that deter physicians from prescribing OxyContin for the treatment of pain. If the lower court's decision is upheld, Ohio physicians will risk becoming defendants in class action suits premised not on the level of professional care they provide but on the risk of abuse of the medications they prescribe. Moreover, it is one thing for a physician's treatment of a patient to be questioned in an individual legal or regulatory setting; it is quite another to be named a defendant in a class action suit and have to defend against a variety of claims from potentially myriad sources, including individuals of whom the doctor has never seen or heard.

Thus, even the possibility of a class action suit will likely lead many, if not most physicians to "act on the perception that they are going to get into trouble."[42] This perception is

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[40] See, e.g., Ann M. Martino, In search of a New Ethic for Treating Patients with Chronic Pain, 26 J. L. Med. & Ethics 332 (discussing various perceived risks of opioid prescribing); J. David Haddox & Gerald M. Aronoff, The Potential for Unintended Consequences from Public Policy Shifts in the Treatment of Pain, 26 J. L. Med. & Ethics 350, 351 (1998) (Commentary); Johnson, supra, at 319-27 (1996); Michael J. Reynolds, Note, Morphine or Malpractice, 15 St. John's J. Legal Comment. 79, 83 (2000); Senate Hearing, supra, at 2 (Statement of Sen. Reed) (citing Brown University study about under-treatment of pain).

[41] Marshall B. Kapp, Treating Medical Charts Near the End of Life, 28 U. Tol. L. Rev. 521, 523 (1997). See also, No Relief, supra ("Doctors are like prairie dogs . . . . One or two will stick their heads up soon as something bad happens to them, they all go underground") (quoting pain specialist Michael Brennan) http://www.salon.com/mwt/feature/2002/04/04/no_relief/index.html.

[42] Rima J. Oken, Note, Curing Healthcare Providers' Failure to Administer Opioids in the Treatment of Severe Pain, 23 Cardozo L. Rev. 1917, 1944 (2002).

only heightened "by national media coverage of a small number of investigations of doctors who have been charged with prescribing opioids excessively."[43] In short, if the class certification order is upheld, many, if not most physicians with pain patients will perceive the risk as too great and will "err on the side of caution" by not prescribing OxyContin at all.

OxyContin has an important place in the physician's toolbox. It is a synthetic, controlled-release opioid analgesic combining the effectiveness and safety of oxycodone (the active ingredient) with the convenience of dosing every 8-12 hours in an oral tablet. Although oxycodone is also found in other prescription opioids like Percodan, Percoset and Tylox, unlike OxyContin these drugs also have co-analgesics, such as aspirin or acetaminophen, which impose a ceiling dose due to their organ toxicity.[44] Moreover, OxyContin is one of only a few long-acting opioids, and is the only controlled-release oxycodone drug on the market, making it "a very valuable addition to the [physician's] armamentarium."[45] "Generally it's much easier to adjust the dose of OxyContin to respond to the clinical needs of the patient in comparison to the other available long-acting pain medications."[46]

Notwithstanding these several significant advantages, it appears that the public's fear of OxyContin is already eroding palliative care in Ohio. The Health Alliance of Greater Cincinnati, the Tri-State's largest hospital group, instructed physicians at its several facilities to "stop

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[43] Gilson & Joranson, supra, at 228.

[44] See Senate Hearing, supra, at 75 (Testimony of Paul D. Goldenheim, M.D.) (noting that large doses of co-analgesics such as aspirin or acetaminophen "may be toxic to the liver, stomach and kidneys").

[45] Id. at 35 (Testimony of John K. Jenkins, M.D.). See also id. at 15 (describing the unique and therapeutically important features of OxyContin).

[46] Id. at 41 (Testimony of Richard Payne, M.D.).

prescribing OxyContin for post-surgical, orthopedic and chronic pain care.[47] If this class action is allowed to proceed, chances are many more health systems and physicians will stop prescribing OxyContin.

B. The Class Action Will Also Deter Physicians From Prescribing Other Schedule II Opioids In Lieu of OxyContin to Treat Pain.

The chilling effect of a class action suit, however, will not stop with OxyContin. "Intimidating doctors from prescribing one opioid will limit their willingness to prescribe any."[48] The abuse potential of OxyContin is no different from any of its 58 pharmaceutical cousins that share its DEA classification.[49] Indeed, the active ingredient of OxyContin is pharmacologically identical to that of other oxycodone-based medications and closely related to all other opioid-derived prescription drugs on Schedule II. It "is as effective as any other opioid for the treatment of pain and has a similar profile of adverse effects, including abuse liability. . . . There is little data that oxycodone per se has any inherently increased abuse liability compared to morphine or other opioids."[50] Many physicians, therefore, will logically conclude that prescribing an opioid other than OxyContin risks the same legal exposure.

Thus, if the class certification order threatens to deter Ohio physicians' use of OxyContin, it is also likely to dissuade them from prescribing any and all Schedule II opioid analgesics – including (but not limited to) fentanyl (Duragesic), hydromorphone (Dilaudid), mepereridine (Demerol), methadone, various forms of oxycodone in addition to OxyContin such

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[47] Hospital Group Restricts OxyContin (Channel Cincinnati television broadcast, Feb. 20, 2001), available at, http://www.channelcincinnati.com/print/477743.detail.html.

[48] Chevlen, supra, at 20.

[49] See Drug Enforcement Administration, Summary of Medical Examiner Reports on Oxycodone-Related Deaths, at http://www.deadiversion.usdoj.gov/drugs_concern/oxycodone/oxycontin7.htm.

[50] Senate Hearing, supra, at 41 (Testimony of Richard Payne, M.D.).

as Percodan, Percoset and Tylox, not to mention morphine and morphine-based medications like MSContin. In short, as a matter of pharmacology (and law), the certification of the classes in this case clears the path for the certification of analogous classes in future cases against any and all Schedule II opioid analgesics, available now or in the future.

But physicians need as wide a range of analgesics as possible to effectively treat pain.[51] One of the cardinal lessons of good pain management is that "one drug does not fit all." Even though opioids derive from the same general chemical family, there are important differences in the ways in which individuals respond to specific drugs, depending on the type and cause of pain, physical condition of the patient, tolerance to side effects, concurrent medications, and many other variables.[52] This class action suit, however, threatens to jeopardize Ohio physicians' willingness to use the full array – or any – of the opioid analgesics at their disposal.[53]

III. ADEQUATE DISCIPLINARY AND REGULATORY MECHANISMS EXIST AT THE FEDERAL AND STATE LEVEL TO POLICE THE PRESCRIBING OF OPIOID ANALGESICS.

Amici have argued that a class action will inhibit physicians from prescribing opioid analgesics thus harming pain patients. But this court should also know that if it overturns the class certification it will not be creating an enforcement gap or otherwise weakening the consumer protections against improper or unscrupulous physician prescribing (or pharmacy dispensing) of Schedule II opioids.

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[51] See, e.g., Foley, supra, at 89 ("There is no 'best choice' of analgesic agent but rather a series of agents").

[52] Senate Hearing, supra, at 41 (Testimony of Richard Payne, M.D.).

[53] Cf. Oxymorons, supra ("The combination of negative press coverage . . . and overzealous law enforcement is making many already leery general practitioners completely unwilling to prescribe much needed medication."); Addicts' Use Hurts Legitimate Patients, supra (noting that physicians are "wary of prescribing" OxyContin "even to patients with . . . debilitating pain problems").

Neither Congress, which has recently held three hearings devoted to OxyContin,[54] nor the Food and Drug Administration, which in January of 2002 convened a blue ribbon advisory committee hearing on OxyContin,[55] has taken action to restrict the availability of OxyContin. The refusal of these bodies to intervene rested primarily on the fact that there exist myriad safeguards at the federal and state levels to protect against inappropriate prescribing or dispensing practices. At the federal level, the FDA and the DEA oversee the development, safety, manufacturing, marketing, prescribing and dispensing of drugs.[56] At the state level exist the Ohio Medical Board,[57] the Pharmacy Board,[58] and Board of Nursing,[59] in addition to law enforcement agencies and special drug task forces.[60]

These bodies collaborate to address medical malfeasance in the treatment of patients and the prescribing of drugs. There is no data to suggest that these agencies, imbued with investigative authority and the power to impose various sanctions, have been unable or unwilling to punish malpractice, negligence or unlawful activity. A class action lawsuit will not aid the

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[54] See Senate Hearing, supra; OxyContin, Hearing Before the House SubComm. on the Depts. Of Commerce, Justice and State, the Judiciary, and Related Agencies, 107th Cong., (2002); OxyContin: Balancing Risks and Benefits, Hearing Before the Senate Comm. on Health, Education, Labor, and Pensions, 107th Cong., 287 (2001).

[55] See Laurence Hammack, FDA Opens Hearings on OxyContin: S.W. Va. Doctor Finds Little Support for Ban on Drug, Roanoke Times, Jan. 31, 2002 (reporting on FDA, Center for Drug Evaluation and Research, Anesthetic and Life Support Drugs Advisory Cmte. Mtg, held Jan. 30-31, 2002, in Gaithersburg, MD), available at http://www.roanoke.com/roatimes/news/story 125166.html.

[56] See generally 21 U.S.C. § 801 et seq.

[57] See Ohio Rev. Code Ann. § 4731 (Anderson 2002). See also http://www5.state.oh.us/med/pdf/BoardMission.pdf (Ohio Medical Board website).

[58] See Ohio Rev. Code Ann. § 4729.02 et seq. (Anderson 2002). See also http://www.state.oh.us/pharmacy/ (Ohio Pharmacy Board website).

[59] See Ohio Rev. Code Ann. § 4723.02 et seq. (Anderson 2002). See also http://www5.state.oh.us/nur/ (Ohio Board of Nursing website).

[60] See, e.g., Warren-Clinton Drug Task Force, http://www.wcdtf.org/ (describing narcotics task force); Cincinnati

work of these regulatory and disciplinary bodies in advancing and protecting public health; rather it will deter law-abiding physicians from adequately treating pain for fear of liability. Unfortunately, patients will pay the price.

CONCLUSION

Amici believe that the information set forth above, culled from clinical experience and scientific research spanning several decades, underscores the magnitude of the error of the decision below and reinforces the principles underlying the legal precedent against class certification. For the foregoing reasons, the order certifying the classes should be reversed.

Dated this 23rd day of December, 2002.

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Police Pharmaceutical Diversion Unit, http://www.cincinnatipolice.org/pdumain.htm (describing narcotics diversion unit); Southern Ohio Law Enforcement Drug Task Force, http://www.officer.com/special_ops/narcotic.htm.

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